United States Public Health Service bicentennial 1798–1998: A focus on oncology pharmacy practice at the National Institutes of Health

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The United States Public Health Service (USPHS), formerly known as the Marine Hospital Service (MHS), was established and signed into law by President John Adams in 1798. The primary duty of the MHS was to render health care to the merchant marine sailors.[1,2] In 1873, hospital stewards of the MHS were required to provide pharmaceutical services such as maintaining an inventory of medications, medical supplies, and hospital instruments and labeling medicinal agents with the name of the patient and directions for use.[3] The 1879 MHS regulations stipulated that a pharmacist or "medical purveyor" be included in the MHS. It is generally accepted that the first MHS medical purveyor was Oscar Oldberg. The requirement for graduation from a pharmacy program was added to the MHS regulations in 1897. [1] The Commissioned Corps, composed of physicians only, was instituted by an act of Congress in 1888. The professions of medicine and pharmacy were the only professions recognized by the MHS in the 19th century.'

MHS pharmacists participated in standardization activities that influenced the formation of the United States Pharmacopoeia. In 1894, under the authority of the Surgeon General, the first pharmacist was stationed at MHS headquarters. The USPHS evolved from the MHS in 1912 because of its expanding developmental role in public health science.[1,3] In 1918, a reserve corps composed of pharmacists, dentists, and engineers was commissioned to serve with the Commissioned Corps of physicians of the USPHS.[3,4]

The Parker Act of 1930 allowed pharmacists to become a part of the regular corps and to be promoted to a grade equivalent to that of an Army Captain.[1,3] As commissioned officers, pharmacists were eligible to provide services during war times, starting with World War II. Pharmacists and physicians served as support for the construction of the China to Burma railroad. They stored quinine and opium, promoted the use of sanitary procedures to prevent epidemics, and advocated the use of dichlorodiphenyltrichloroethane (DDT) to control the insect population.[3] In addition, their duties included providing quarantine services that entailed the inspection of ships and planes to prevent the importation of foreign communicable diseases.' Starting in 1944, pharmacists were allowed to be promoted to pharmacy director, a rank that is equivalent to an Army Colonel, because of their continuing influence on medical practice.[1,3]

A pharmacy service was organized in 1945 to oversee the clinics and hospitals of the USPHS. Raymond D Kinsey was the first USPHS pharmacy officer to reach the rank of pharmacist director. Pharmacists were valued not only for their apothecary practices but also for their administrative and management skills. In 1971, Edgar Duncan, was the first pharmacist to be promoted to the rank of Assistant Surgeon General (a rank corresponding to Army Brigadier General or Navy Rear Admiral). In 1979, Congress decreed that the Chief Pharmacy Officer was entitled to the rank of Assistant Surgeon General.[3]

In the last 30 years, USPHS commissioned officer and civil service pharmacists at the National Institutes of Health (NIH) Clinical Center (CC), the 350-bed federal research hospital that supports the intramural research program of the NIH, have been instrumental in expanding the role of the pharmacist from the management and dispensing of medications to the provision of patient-focused pharmaceutical care services (see *Sidebar*) and

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research support.[5] NIH, comprised of 24 separate institutes and centers, is one of the eight operating divisions of the USPHS and is the primary biomedical research arm of the federal government.

The CC pharmacy provides a full range of services, including traditional unit dose and intravenous additive programs, pharmaceutical care, an outpatient pharmacy, and a manufacturing unit called the Pharmaceutical Development Section (PDS). The PDS not only provides full manufacturing and analytical support for investigational new drug applications but also helps design drug randomization and blinding schemes in conjunction with the clinical investigators_

The Pharmacy Department is staffed with ~ 100 pharmacists, scientists, chemists, technicians, and other support personnel. The CC pharmacy was a leader in offering centralized intravenous additive services to inpatients, and many of the early compatibility and stability studies of investigational drugs were performed by the PDS. The CC is also equipped with a hospital-wide medical information system which not only allows direct physician input of medication orders with instant transmission to the pharmacy, but also allows pharmacists and other health-care professionals to have access to patient information from any of the many terminals located throughout the hospital.

A major portion of the resources of the department are dedicated to providing services to National Cancer Institute (NCI) patients. Three clinical pharmacy specialists, five' satellite pharmacists, and two technicians provide specialized oncology pharmacy services. Backup is provided by the central pharmacy service. In addition to the traditional clinical services, oncology pharmacists ensure that drug regimens comply with all protocol specifications before preparation and dispensing. This service has been offered for over 15 years and is integral to the hospital's system to prevent chemotherapy misadventures. Clinical pharmacy specialists also counsel patients on their chemotherapy as well as provide pain and emesis management. Voting membership on the NCI Institutional Review Board also ensures early pharmacy input and a review of NCI intramural studies.

Oncology pharmacists at the CC have made many other contributions to the pharmacy profession as well as to oncology practice. CC pharmacists serve on the supportive care and drug information panel of the NCI Physician's Data Query online cancer information service and on the Board of Pharmaceutical Specialties Council on Oncology Pharmacy Practice. The first recommendations for the safe handling of injectable antineoplastic drugs products and for the disposal of antineoplastic waste were authored by CC pharmacists in conjunction with the NIH Division of Safety.[6,7] A videotape based on the handling and disposal articles and 3 pictorial color pamphlet were distributed nationally.[8] The color pamphlet (under revision) is available at the NIH Division of Safety website (http://www.nih.gov/od/ors/ds/pubs/cyto/). The pamphlet was a joint effort of the NIH Division of Safety, the CC Pharmacy Department, and the NIH CC Cancer Nursing Service; thousands have been distributed nationally.

More recently, CC pharmacists published two articles that have had national impact. Standardizing the expression and nomenclature of cancer treatment regimens suggests ways to prevent vague expressions of chemotherapy regimens in protocol documents, publications, and product labels.' All NCI-supported studies are required to conform to these guidelines." Another article describes the handling of gene-transfer products by the NIH CC Pharmacy Department." This paper is the first to describe pharmacy procedures for these new products and has become the model for other pharmacies that deal with gene therapy products.

The oncology clinical pharmacy specialists are part of a clinical team that includes services to areas such as critical care, neurology, bone marrow transplant, mental heath, drug information, infectious diseases, and clinical pharmacokinetics research. Four residencies, including an American Society of Health System Pharmacists-accredited oncology specialty residency, are offered by the Pharmacy Department. The CC Pharmacy Department website can be accessed at http://www.cc.nih.gov/phar/. Radiopharmacists, who provide approved and investigational pharmacy products to NCI patients for both diagnostic and therapeutic purposes, are part of the CC Nuclear Medicine Department.

The research program at NIH also employs pharmacists in many of its 17 institutes. Pharmacists in the Pharmaceutical Management Branch of NCI are involved in anticancer drug development, protocol development, the collection of clinical data, the distribution of NCI investigational drugs, and Treatment Referral Center protocols.[11] Also, the NCI intramural program has a pharmacokinetics laboratory where pharmacists perform both clinical and basic research. Over the years, pharmacists have contributed to NCI intramural studies that have led to approval by the Food and Drug Administration of many anticancer agents, including doxorubicin, cisplatin, tamoxifen, levamisole, aldesleukin, paclitaxel, and topotecan.[12]

In summary, the changes that have occurred in pharmacy practice over the last 200 years are a reflection of those that took place in the USPHS. "Hospital stewards" whose duties included medication labeling in the late 1800s have evolved into clinical pharmacy specialists who not only provide medications to patients but provide pharmaceutical care and research support to the NIH. The USPHS bicentennial is a time to celebrate the

progress of pharmacy practice during the last two centuries.

Additional information on the USPHS can be obtained at the following intemet addresses:

NIH: www.nih.gov

Centers for Disease Control and Prevention: www.cdc.gov

USPHS: www.os.dhhs.gov/phs

USPHS Commissioned Corps: www.os.dhhs.gov/phs/corps

SIDEBAR

CAPT Clarence Fortner (USPHS, Ret), one of the original pioneers of oncology clinical pharmacy practice, provided insight into the development of clinical pharmacy practice. He is currently the Director of Scientific Affairs, North America Market Region for Pharmacia and Upjohn.

In June 1968, clinical pharmacy was not only a new term but also a new concept. CAPT Fortner, the director of pharmacy at the Baltimore Cancer Research Center (BCRC), a unit of the NCI located within a USPHS hospital, was assigned with James Cradock (currently vice president of Ben Venue Labs) and Jim Menzie (presently a radiologist) to steer pharmacy in a new direction. Fortner, Cradock, and Menzie had Masters of Pharmacology degrees in addition to their pharmacy degrees. Their objective was to "involve pharmacists in patient care [and] remove ... [them] from the traditional role 'of dispensing pharmacists. "

These individuals initiated the expansion of pharmacy services by being "diplomatically aggressive." Pharmacists participated in patient care rounds and were successful in convincing the nurses and physicians that pharmacists do more than "lick, stick, and pour." They performed interventions, answered questions, monitored drug therapy, maintained patient profiles, and provided drug information. In addition, they implemented the problem-oriented approach for solving medical problems that eventually evolved into SOAP (subjective, objective, assessment, plan) notes.

Pharmacists interviewed newly admitted hospitalized patients for drug and allergy histories and performed clinical research. They were involved with the early clinical studies demonstrating that empirical use of cephalothin, carbenicillin, and gentamicin can improve outcomes in patients with leukemia and febrile neutropenia. Previously, many patients with this syndrome died of infection rather than from their cancer. Pharmacists closely monitored gentamicin levels and intervened with dosage adjustments when appropriate Pharmacists also **ensured** that the antibiotic regimen was modified as per protocol when cult ures became available. This empiric triple antibiotic therapy was the standard of practice for many years in the treatment of febrile neutropenic cancer patients.

One of the major accomplishments of clinical pharmacists at the BCRC was to improve the adherence of patients to medication. One study in particular was integral to changing the beliefs of physicians about the role of the pharmacist. Pharmacists were charged with counseling patients on the use of oral antibiotics for gut sterilization. Before pharmacists intervened, the patient compliance rate was 65%. After pharmacist counseling, the compliance rate increased to **-90%.** These results were proven repeatedly when pharmacists stopped counseling patients and the adherence rate dropped to -65%. Upon reinstitution of the counseling, patient adherence to the antibiotic regimen rebounded to **-90%.**

The role of the pharmacist at the BCRC expanded from preparing and dispensing medication to performing drug and allergy histories, counseling patients, participating in codes to researching the new clinical uses of drugs, and increasing awareness of the integral role that pharmacists have in patient care. CAPT Fortner later became the Section Head of the NCI Drug Management and Authorization Section.

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